Remarks

Claim 23 has been cancelled, claims 1, 2, 10-13 and 15-22 have been amended, and claims 24-31 have been added. Support for the foregoing claim amendments and new claims may be found throughout the specification, for example at page 14, line 2 through page 20, line 4, at page 43 line 13 through page 45 line 4, Table A, in the sequence listing and in the original claims. No new matter enters by these amendments. Upon entry of the foregoing amendments, claims 1, 2, 10-13, 15-22, and 24-31 are pending in the application.

The specification has been amended to explicitly reference the Sequence Listing on computer readable form in the present application. Support for this amendment can be found in the Sequence Listing on computer readable form filed on April 28, 1999. No new matter enters by this amendment.

I. Priority

Applicants disagree with the Examiner's contention that "applicant admitted on page 1 of the response filed 9/27/01 that SEQ ID NO's 4, 14, 27, 298, 311, 356, and 569 are not supported by the Provisional..." Office Action at page 2. Applicants note that it is believed that the Examiner refers to Applicants' Response that was filed on September 24, 2001, for which a courtesy copy of a date-stamped postcard is enclosed. Moreover, Applicants further note that in the response filed on September 24, 2001, Applicants merely stated that "SEQ ID Nos: 4, 14, 27, 298, 311, 356, and 569 do not have corresponding SEQ ID NOs in the provisional application." Response to Office Action filed September 24, 2001 at page 1. However, while disagreeing with the Examiner's contention, Applicants acknowledge the Examiner's stated position that claims 1-2, 11, 13, 15, 17-20, and 22-23, which recited these sequences prior to the present amendment, were "accorded priority only to the filing date of the instant application, as of 4/28/1999." Office Action at page 2.

II. 35 U.S.C. §112, Written Description

Claims 1, 2, 10-13, and 15-23 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being described in the specification "in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action at page 2.

The Examiner, acknowledging that "[s]equences consisting of SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619 meet the written description requirement," does not dispute that Applicants had possession of and have adequately described the claimed SEQ ID NOs. *Id.* at pages 2-3. However, the Examiner argues that Applicants have allegedly not described the claimed nucleic acid molecules. The basis for the Examiner's rejection is that the specification allegedly "sets forth a list of possible variations for the inventive sequences, . . .but does not actually describe, by sequence or structure, any of the variations, nor does the specification disclose any longer sequences (e.g. genomic) which may comprise the claimed sequences." Office Action at page 3. According to the Examiner, the sequences recited in the claims do not appear to comprise ORF's or encode proteins, and encompass much larger sequences which may encode different proteins from this recited. Apparently, the Examiner contends that the specification allegedly "provides insufficient written description to support the genus encompassed by the claim." *Id.* at page 3. Applicants respectfully disagree.

This argument flies in the face of the existing patent jurisprudence. It is well-established law that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986). The very nature of "unspecified ingredients" is that they are <u>not</u> specified or described. The Examiner attempts to turn the legal meaning of "comprising" on its head by requiring Applicants to describe hypothetical claim elements. Applicants' claims, as amended, recite the required nucleic acid sequences, define the enzyme or fragment thereof encoded by the sequences, and recite hybridization parameters. Applicants' claims do not recite open

reading frames and, accordingly, need not describe them. Applicants need only describe the claimed invention, and have done so in the present application.

As Applicants have previously pointed out, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, complements and variations thereof, sequences that hybridize to the claimed nucleic acid molecules under the recited conditions, as well as the enzymes they encode. Applicants have indeed demonstrated possession of the claimed invention.

For example, the specification describes gene sequences, corresponding sequences from other species, mutated sequences, SNPs, polymorphic sequences, promoter sequences, exogenous sequences, and so forth (*see, e.g.,* specification at page 23, line 12 through page 26, line 20; page 46, line 6 through page 48, line 5; page 53, line 10 through page 54, line 22; and page 65, line 21 through page 74, line 18). The specification also describes appropriate hybridization conditions (*see, e.g.,* specification at 43, line 13 through page 45, line 4); nucleic acid molecules comprising nucleic acid sequences having conservative variations or encoding amino acid sequences having conservative substitutions (*see, e.g.,* specification at page 48, line 6 through page 50, line 6); fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 59, lines 4-15); plant homologue proteins (*see, e.g.,* specification at page 59, line 16 through page 60, line 6); site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.,* specification at page 87, line 12 through page 89, line 3); vectors comprising the claimed nucleic acid

molecules and methods of transforming plants (*see, e.g.*, specification 93, line 1 through page 107, line 19); and construction of cDNA libraries using the claimed nucleic acid molecules (*see, e.g.*, specification at page 152, line 13 through page 222, line 7 (Examples 1-3)).

Thus, Applicants respectfully disagree with the Examiner's contention that despite the numerous variations of the claimed nucleic acid molecules described in the present specification, "with the exception of sequences consisting of SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides". Office Action at page 4. The Examiner appears to assert that each nucleic acid molecule within a claimed genus must be described by its complete structure. This assertion is unfounded. The test, promulgated by the Federal Circuit, stipulates that where a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus, written description is satisfied. *See Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). In the present case, Applicants have satisfied that test for written description by providing a structural feature, namely nucleic acid molecules that distinguish members of the claimed genus from non-members.

In particular, Applicants have disclosed, for example, the nucleotide sequences of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, and their complements, as well as recited specific hybridization conditions. The common structural feature (the nucleotide sequence of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, 619 and their complements) is shared by <u>every</u> nucleic acid molecule in the claimed genera, and this feature distinguishes members of the claimed genera from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1.[1] If a nucleic acid molecule does not contain

[1] The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule such as an mRNA comprises the nucleotide sequence of SEQ ID NO:

Footnote continued on next page

SEQ ID NO: 1, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 1 or it does not. Accordingly, the standard elucidated in *Lilly* for the written description requirement has been met.

Moreover, closely related nucleic acid molecules falling within the scope of the present claims are readily identifiable - they either hybridize under the claimed conditions to SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569 and 619 (or complements thereof) or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

Applicants also disagree with the Examiner's application and characterization of Baker with respect to Applicants' disclosure. Office Action at pages 3-4. First, the Examiner's assertion that "Applicant acknowledges that BAKER et al. . . is directed to controversy in the art over prediction of function based on homology alone" misconstrues Applicants' stated position. *See* Office Action at page 3 (citations omitted). In fact, the actual statement made by Applicants in the Amendment and Response filed October 17, 2002, was that "Applicants contend that this article is directed to the controversy in the art in general over prediction of function based on homology alone, but does not take into consideration Applicants' disclosure." Response filed October 17, 2002, at page 5 (emphasis in original). The Examiner relies on Baker to support a broad allegation of unpredictability in the art, but has not presented any support or given any reason of how Baker is specifically applicable to Applicants' invention, or why this reference would support a written description rejection under 35 U.S.C. § 112, first paragraph. This does not form a basis for a proper written description rejection. *See* MPEP § 2163.

Footnote continued from previous page

4, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 4. *See, e.g.*, claim 13.

In particular, the fundamental factual inquiry for satisfying the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, that applicants were in possession of the invention as now claimed. See, *e.g.*, *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997), MPEP § 2163.02. Moreover, the Examiner has failed to provide reasons why a person skilled in the art at the time the application was filed would not have recognized that Applicants were in possession of the invention as claimed in view of the disclosure of the application as filed. "A general allegation of 'unpredictability in the art' is not a sufficient reason to support a rejection for lack of adequate written description." MPEP § 2163.

For these same reasons, the Examiner's rejection of claims 1 and 22 for lack of adequate written description, *see* Office Action at page 4, must also fail as it too overreaches the requirements of the law. Simply put, Applicants have described the invention encompassed by the claims. No more is required.

The Examiner has offered no evidence to demonstrate, in light of Applicants' disclosure, why one of ordinary skill in the art would reasonably doubt that the invention encompassed by Applicants' has not been adequately described in the present disclosure. As such, the Examiner has not met the burden to impose a written description rejection.

Based on the foregoing, Applicants respectfully submit that the currently pending claims are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112. As such, reconsideration and withdrawal of the outstanding written description rejection are respectfully requested.

III. 35 U.S.C. § 102, Anticipation

Claim 10 was rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Uchimiya (NCBI accession number D43256), as supported by Meinkoth. Office Action at page 5. According to the Examiner, "the melting point of a duplex between SEQ ID

NO: 619 and Uchimiya's sequence would be 76.5°C at 0.33M salt, therefore UCHIMIYA's sequence would inherently hybridize to SEQ ID NO: 619 or its complement under the recited conditions." *Id.*

A rejection under 35 U.S.C. § 102(a) is only proper if, *inter alia*, an anticipatory reference is available publicly. The Office has submitted no evidence that D43256 was available to the public prior to Applicants' filing date. The Office apparently relies on the date the nucleotide sequence was submitted to the NCBI database (*i.e.,* May 4, 1998) to establish the reference date under §102(a). However, there is no evidence that the Uchimiya sequence was published or otherwise available to the public prior to Applicants' filing date.

Although Applicants disagree with the Examiner's application of the Uchimiya reference, in order to facilitate prosecution, Applicants have amended claim 10, rendering this anticipation rejection moot. Based on the foregoing, Applicants respectfully submit that the rejection of Claim 10 on the basis of Uchimiya in light of Meinkoth has been rendered moot. Reconsideration and withdrawal of this rejection under 35 U.S.C. §102(a) is respectfully requested.

Claims 1 and 10 were rejected under 35 U.S.C. § 102(a) and (b) as allegedly being anticipated by Katsurada (NCBI accession number AB007907), as supported by Meinkoth. Office Action at page 6. According to the Office, "the melting point of a duplex between SEQ ID NO: 27 and Katsurada's sequence would be 65.9°C at 0.33M salt, therefore KATSURADA's sequence would inherently hybridize to SEQ ID NO: 27 under the recited conditions." *Id.*

A rejection under 35 U.S.C. § 102(a) is only proper if, *inter alia*, an anticipatory reference is available publicly. The Office has submitted no evidence that AB007907 was available to the public prior to Applicants' filing date. The Office apparently relies on the date the nucleotide sequence was allegedly submitted to the NCBI database (*i.e.,* October 15, 1997) to establish the reference date under §102(a). However, there is no evidence that the Katsurada sequence was published or otherwise available to the public prior to Applicants' filing date. Indeed, Applicants respectfully point out that page 2 of

the NCBI Katsurada reference provided by the Office states "Revised: October 24, 2001." Accordingly, Applicants respectfully submit that the rejection of claims 1 and 10 under 35 U.S.C. § 102(a) over Katsurada is improper and should be withdrawn.

Nonetheless, although disagreeing with the Office's application of the Katsurada reference, in order to facilitate prosecution, Applicants have amended claims 1 and 10, thereby rendering this anticipation rejection moot. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §102(a) and (b) is respectfully requested.

Claim 10 was rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Walbot (NCBI accession number AI586588), as supported by Meinkoth. Office Action at page 7. According to the Office, "the melting point of a duplex between SEQ ID NO: 356 and WALBOT's sequence would be 73.9°C at 0.33M salt, therefore WALBOT's sequence would inherently hybridize to SEQ ID NO: 356 under the recited conditions." *Id.*

A rejection under 35 U.S.C. § 102(a) is only proper if, *inter alia*, an anticipatory reference is available publicly. The Office has submitted no evidence that AI586588 was available to the public prior to Applicants' filing date. The Office apparently relies on the date the nucleotide sequence was allegedly submitted to the NCBI database (*i.e.*, April 7, 1999) to establish the reference date under §102(a). However, there is no evidence that the Walbot sequence was published or otherwise available to the public prior to Applicants' filing date. Indeed, Applicants respectfully point out that page 2 of the NCBI Walbot reference provided by the Office states "Revised: July 5, 2002." Accordingly, Applicants respectfully submit that the rejection of claim 10 under 35 U.S.C. § 102(a) over Walbot is improper and should be withdrawn.

Nonetheless, although disagreeing with the Office's application of the Walbot reference, in order to facilitate prosecution, Applicants have amended claim 10, thereby rendering this anticipation rejection moot. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §102(a) is respectfully requested.

Claims 1 and 10 were rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Bouvier (NCBI accession number Y15781), as supported by Meinkoth.

Office Action at page 8. According to the Office, "the melting point of a duplex between SEQ ID NO: 356 and BOUVIER's sequence would be 55.4°C at 0.33M salt, therefore BOUVIER's sequence would inherently hybridize to SEQ ID NO: 356 under the recited conditions." *Id.*

A rejection under 35 U.S.C. § 102(a) is only proper if, *inter alia*, an anticipatory reference is available publicly. The Office has submitted no evidence that Y15781 was available to the public prior to Applicants' filing date. To the contrary, the February 26, 2002 date appearing at the top of the NCBI entry, when compared with Applicants' earlier filing date, evidences the fact that Bouvier provides a legally insufficient basis for a rejection under 35 U.S.C. §102(a). Accordingly, on this basis, Applicants respectfully submit that the rejection of claims 1 and 10 under 35 U.S.C. § 102(a) over Bouvier is improper and should be withdrawn.

Nonetheless, although disagreeing with the Office's application of the Bouvier reference, in order to facilitate prosecution, Applicants have amended claims 1 and 10, thereby rendering this anticipation rejection moot. Reconsideration and withdrawal of this rejection under 35 U.S.C. §102(a) is respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe that any fees in addition to those provided for in the accompanying documents, are due at this time. However, if any fees under 37 C.F.R. 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2387, referencing docket number 16517.216.

Respectfully submitted,

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